

# State of Global Life-Sciences Innovation Policy

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International Think Tank Dialogue  
New York City  
September 11, 2017

# About ITIF

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- Independent, nonpartisan research and education institute focusing on intersection of technological innovation and public policy, including:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Trade and globalization
  - Life sciences, agricultural biotech, and energy
- Mission to formulate and promote policy solutions that accelerate innovation and boost productivity
- Ranked by University of Pennsylvania as top science and technology think tank in United States and number two in world

# A Golden Age of Biomedical Innovation

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About 7,000 Medicines Under Development Globally



**CANCERS**  
836



**HEART DISEASE & STROKE**  
190



**ALZHEIMER'S DISEASE**  
77



**AUTOIMMUNE DISEASES**  
311



**DIABETES**  
171



**MENTAL HEALTH DISORDERS**  
135



**RARE DISEASES**  
566

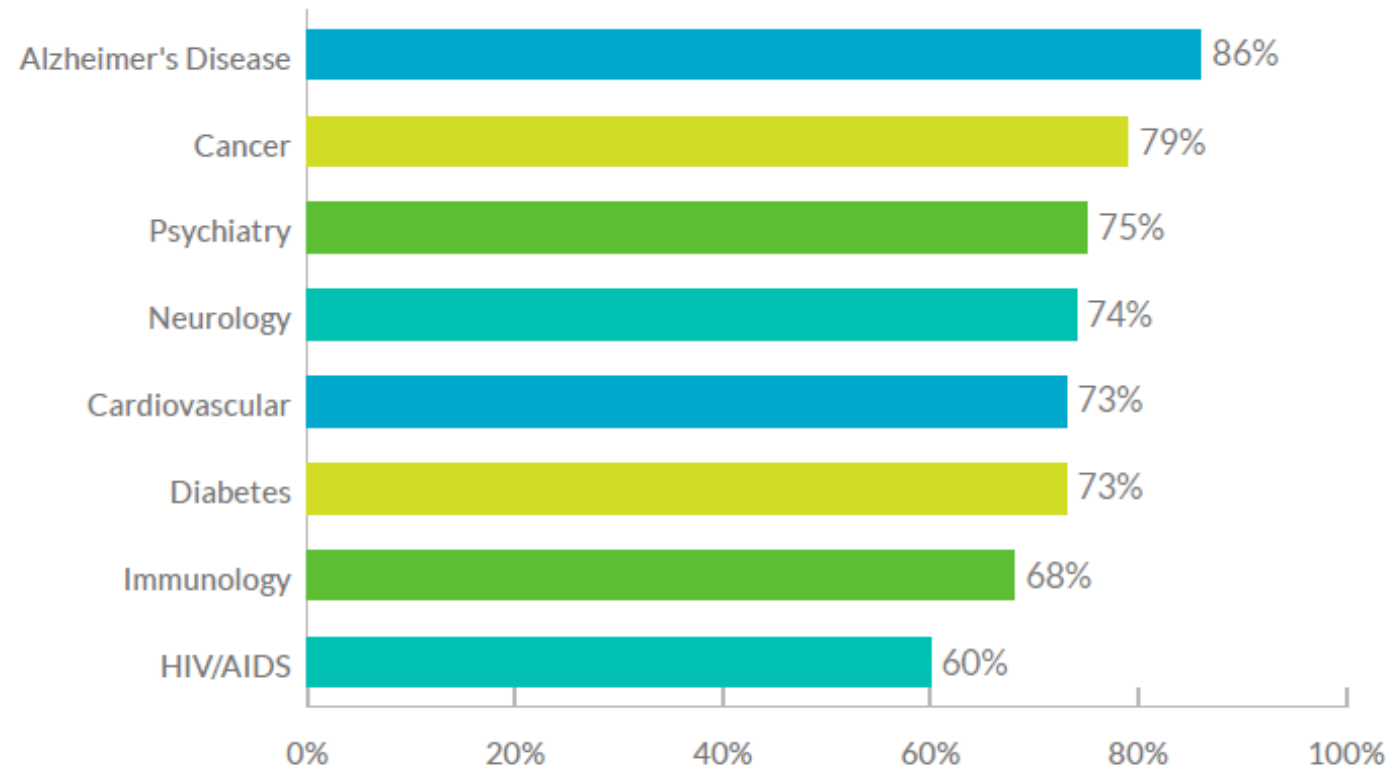


**NEUROLOGICAL DISORDERS**  
420

Source: PhRMA, *Chart Pack: Biopharmaceuticals in Perspective, Spring 2017*

# Developing New-to-the-world Treatments

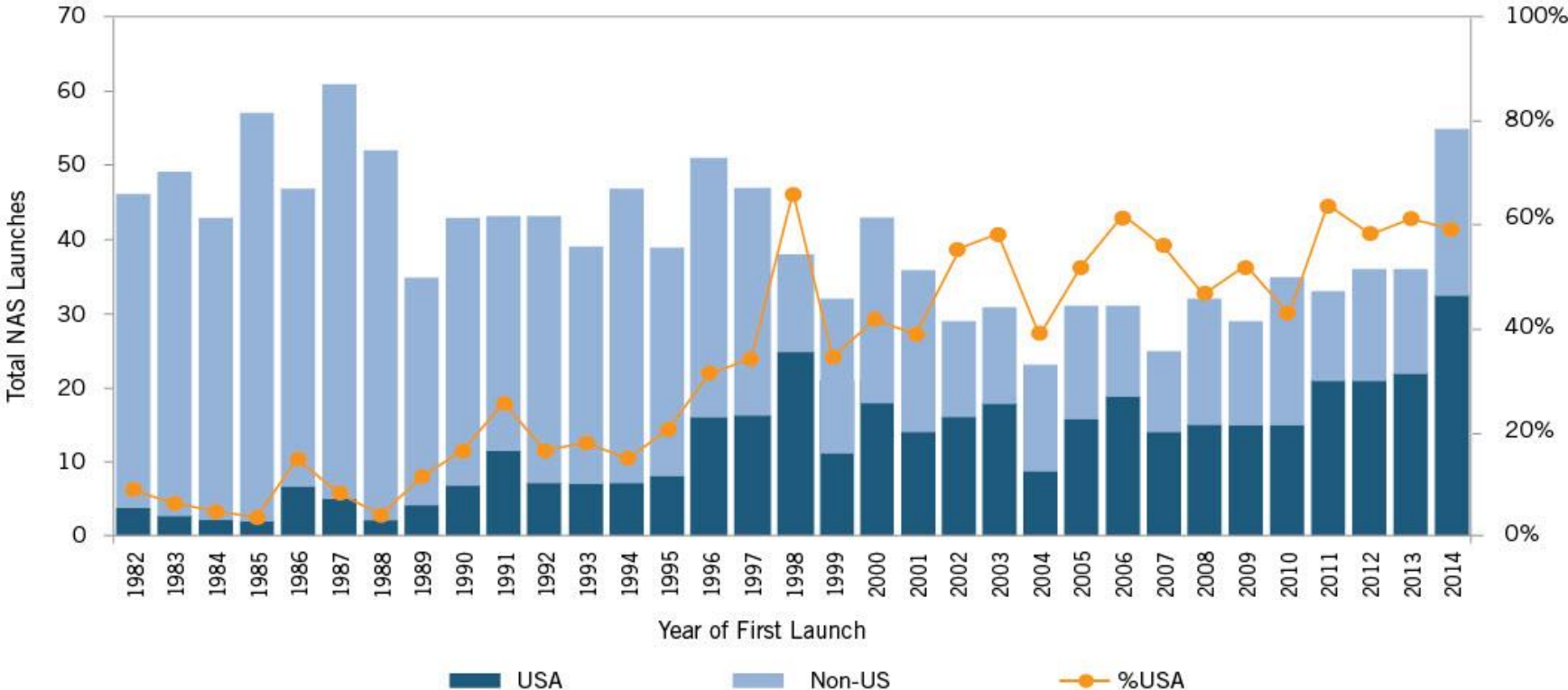
Percentage of Products in Clinical Development and Regulatory Review That Are Potentially First-in-Class, Selected Therapeutic Areas, 2016



Source: PhRMA, *Chart Pack: Biopharmaceuticals in Perspective, Spring 2017*

# U.S. Leads in Global Life-Sciences Innovation

U.S. Share of New Active Substances (NAS) Launched First on World Market



Source: John K. Jenkins, M.D., "CDER New Drug Review: 2015 Update"

# Keys to Life-Sciences Innovation Leadership

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1. Robust public/private investment in biomedical research.
2. Aggressive incentives to encourage investment. (E.g. R&D tax credit, Orphan Drug Tax Credit)
3. Robust intellectual property protections.
4. Pricing/reimbursement system allowing innovators to earn sufficient revenues.
5. Effective regulatory/drug approval system.

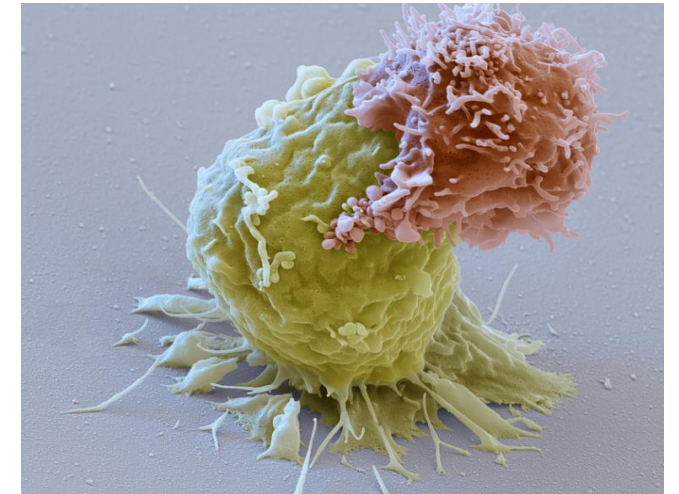


Image of a CAR-T cell (reddish) attacking a leukemia cell (green).

# The Global Political Economy of Life-Sciences Innovation

## 1. “Drug populists” who distrust private innovation.

- Assert that biopharma companies charge too much for drugs.
- Want government to take leading role in drug development.
- Advocate for price controls, weaker patent protections, and shorter data-exclusivity periods.

## 2. “Drug libertarians” who distrust public investment.

- Assert that government investment in scientific research is inefficient and wasteful.
- Want to limit government-supported life-sciences research in order to shrink government and redistribute \$\$ to taxpayers.
- Think private sector would invest enough in basic research.



**Why Life-Sciences Innovation Is Politically “Purple”—and How Partisans Get It Wrong**

BY ROBERT D. ATKINSON | FEBRUARY 2016

*It is time for a renewed bipartisan consensus recognizing that both public and private sectors have their own distinct and important roles in ensuring a robust American biopharma innovation ecosystem.*

The United States has long had the world’s most effective and competitive system for discovering and developing new drugs—and for more than a half century, there has been a bipartisan consensus that there are two reasons for that success: First, the federal government provides robust funding for scientific research, mostly through the National Institutes of Health (NIH). Second, the U.S. system encourages vigorous innovation in the private sector by providing strong intellectual property protections and a drug reimbursement system that together allow companies to earn sufficient revenues to reinvest in highly risky research and development.<sup>1</sup> But today that consensus is fraying as populists on the left and libertarians on the right question both the policy means and the end result. If the center cannot hold and the longstanding bipartisan policy framework falls apart, then the future of U.S. biomedical innovation will be in peril.

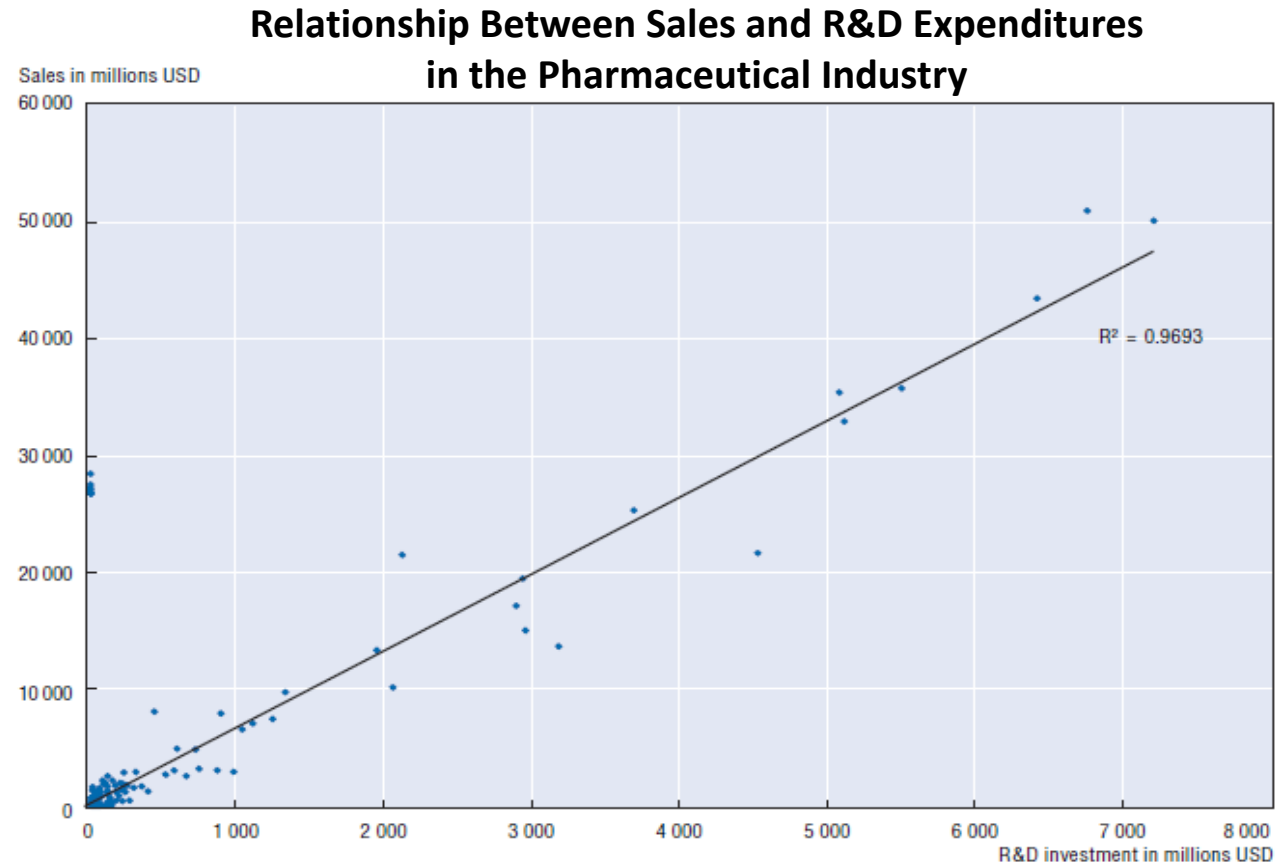
**INTRODUCTION**

Many on the left have long voiced concerns about drug prices, but most of them have acknowledged that the U.S. system for discovering and developing drugs has worked well and that America has benefited by constantly improving drugs and fielding a globally competitive biopharmaceutical industry (biopharma). Now that view is under attack from an ascendant camp that may be fairly described as “drug populists.” These left-wing advocates complain that biopharma companies charge too much for drugs, and that government should impose price controls, weaken patent protections, and shorten the term of intellectual property protection for the clinical test data related to new biologic drugs (known as “data exclusivity”). This is part and parcel of a larger policy agenda for the federal government to assume a significantly increased role in drug development, and the biopharma industry to be significantly hemmed in. These populists embrace the view that health care is a fundamental human right, and they deeply distrust the private sector, which

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# Reasonable Prices Are Vital for Life-Sciences Innovation

- OECD: “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.”
- A statistically significant relationship exists between a bio-pharma enterprise’s profits from the previous year and its R&D expenditures in the current year.



Source: OECD, *Pharmaceutical Pricing Policies in a Global Market*



# Reasonable Prices Are Vital for Life-Sciences Innovation

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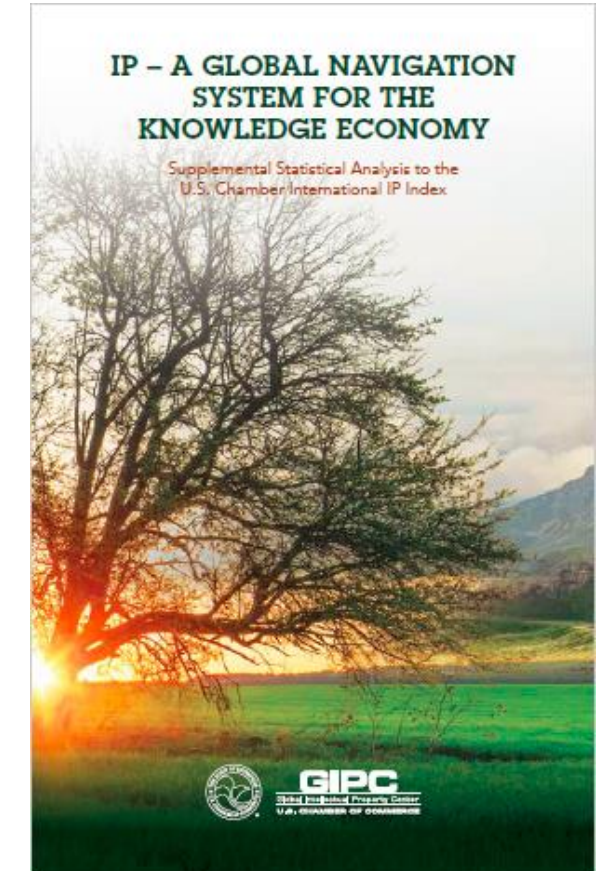
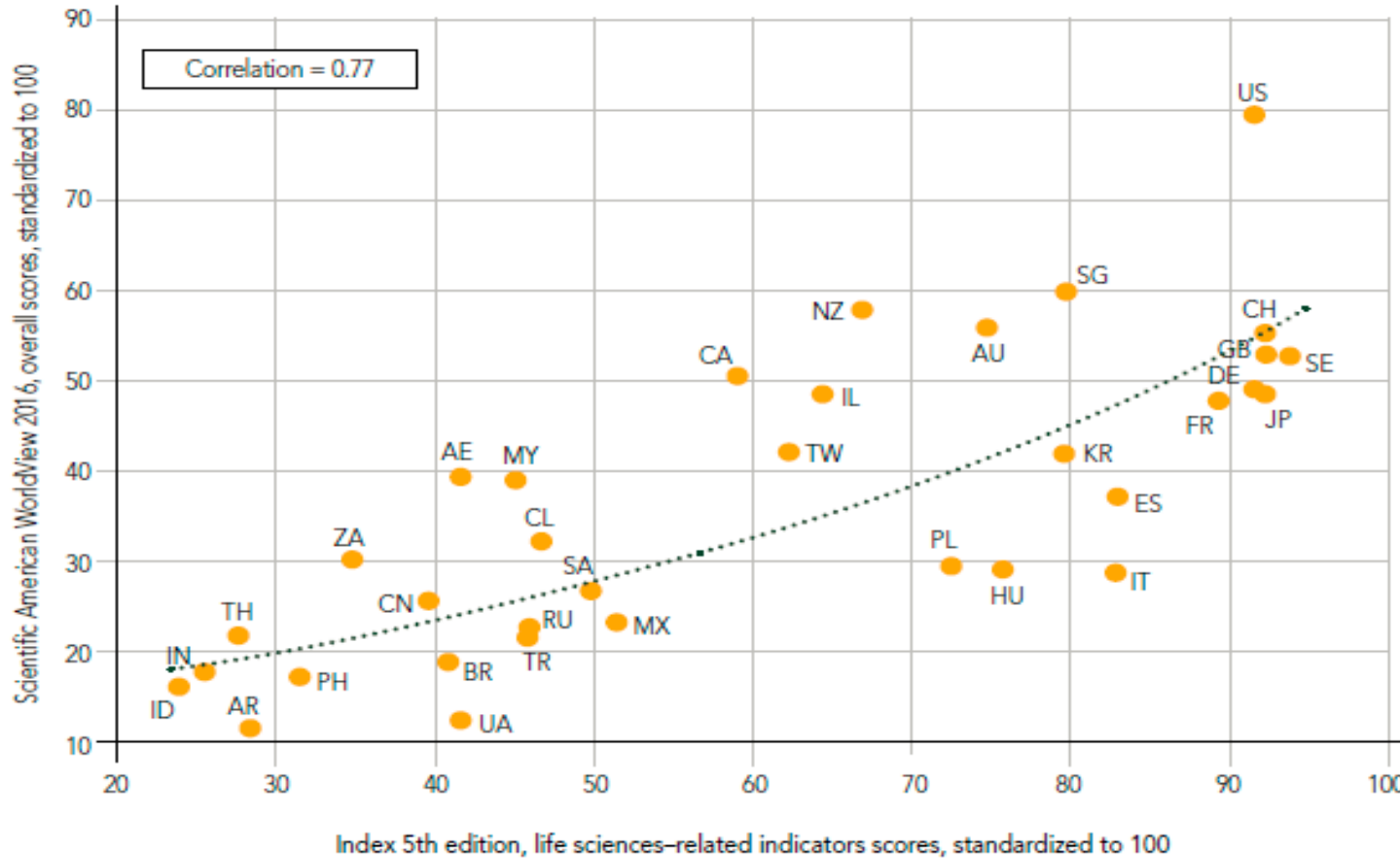
1. Vernon estimates a policy which would regulate U.S. prices in a way equivalent to the rest of the world would result in a decline in firms' R&D expenditures in the range of 23-33%.
2. Civan estimates a 50% drop in U.S. drug prices would result in the number of drugs in the development pipeline dropping up to 24%.



Source: Golec and Vernon, *Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms*

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# Leadership in Biotechnological Innovation Requires Robust IP Protection

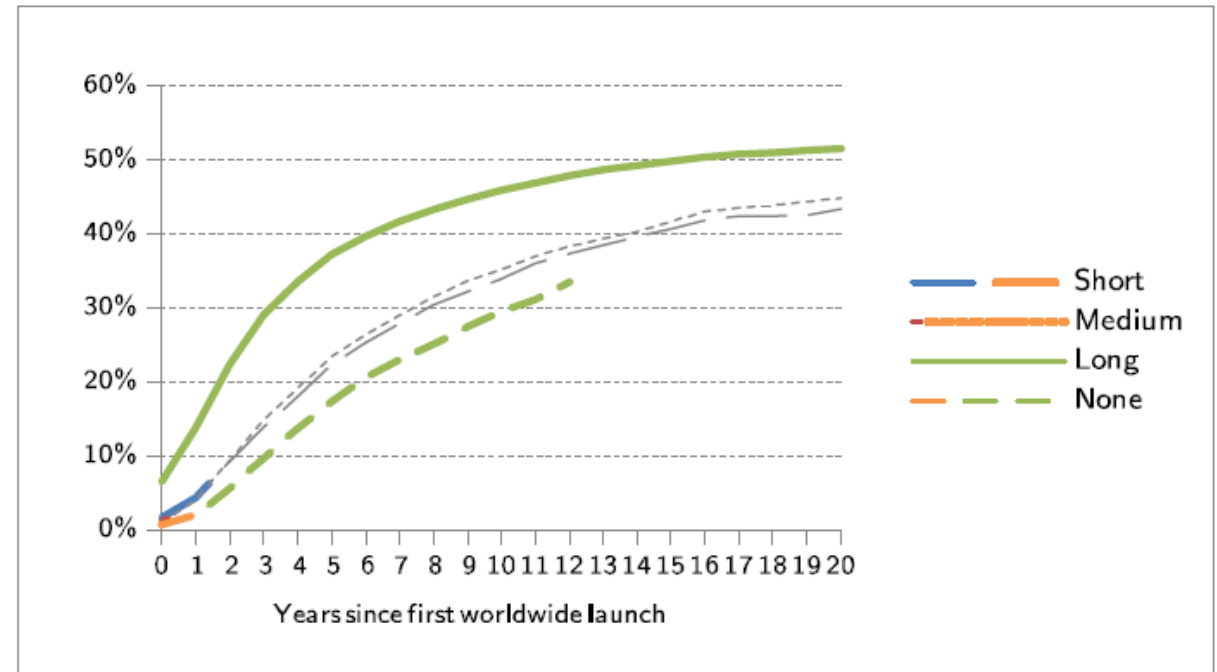


Source: Global Intellectual Property Center, *IP-A Global Navigation Center for the Knowledge Economy*

# Factors Affecting Drug Launch in Countries

- New study of 642 new drug launches in 76 countries from 1983 to 2002.
- Finds speed/extent of diffusion strongly associated with countries' patent and price regulation schemes.
- Moving from a regime of no product patents to long product-patent terms reduces drug launch lags by 55%.

Fraction of Drugs Launched by Patent Regime

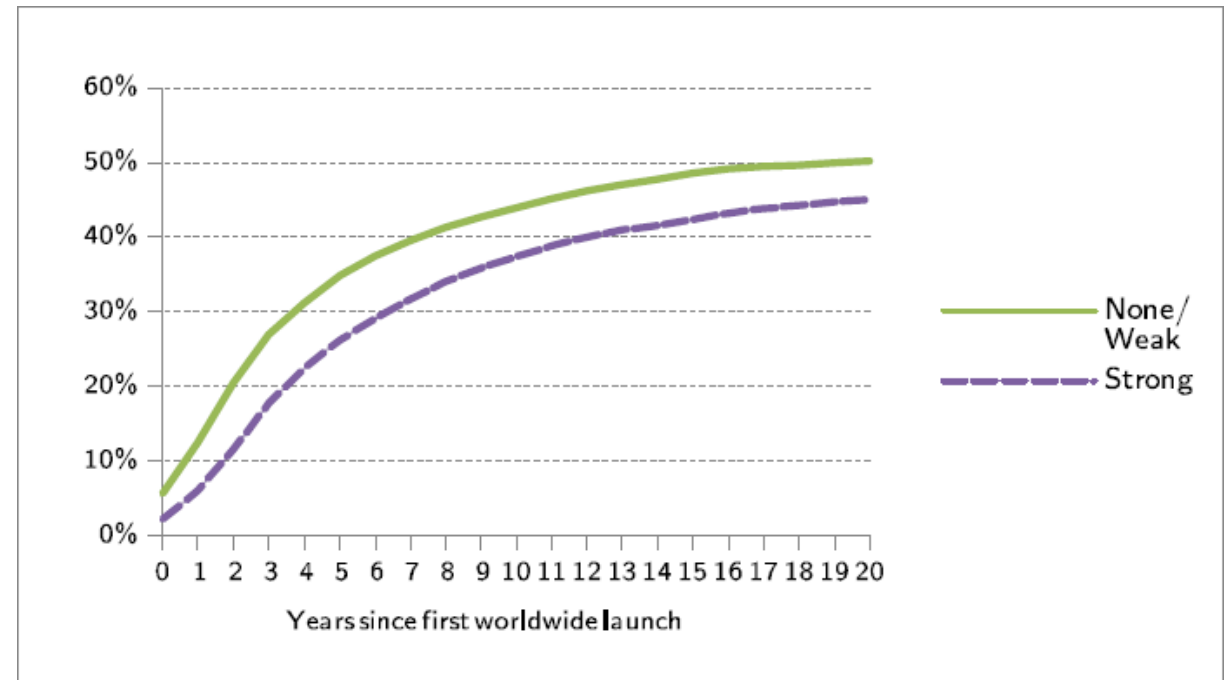


Source: Cockburn, Lanjouw, and Schankerman, *Patents and The Global Diffusion of New Drugs*, 2016

# Factors Affecting Drug Launch in Countries

- Countries adopting strong price controls experience “significantly longer lags.”
- Introducing price controls increases drug launch lags 25-80%.

Fraction of Drugs Launched by Price Controls



Source: Cockburn, Lanjouw, and Schankerman, *Patents and The Global Diffusion of New Drugs*

# Patents and Drug Prices

- Duggal et al. assessed 6,000+ products consisting of 1,000+ molecules in India.
- Estimates molecules receiving a patent saw average price increase of just 3–6 percent.

*“Our results demonstrate that the implementation of product patents for India did not cause either the large increases in pharmaceutical prices or the dramatic consolidation of the market that some predicted prior to its enactment.”*

Source: Duggan, Grathwaite, and Goyal, *The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India*

## The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India<sup>1</sup>

By MARK DUGGAN, CRAIG GARTHWAITE, AND APARAJITA GOYAL<sup>2</sup>

*In 2005, as the result of a World Trade Organization mandate, India implemented a patent reform for pharmaceuticals that was intended to comply with the 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS). Exploiting variation in the timing of patent decisions, we estimate that a molecule receiving a patent experienced an average price increase of just 3–6 percent, with larger increases for more recently developed molecules and for those produced by just one firm when the patent system began. Our results also show little impact on quantities sold or on the number of pharmaceutical firms operating in the market. (JEL K33, L11, L13, L65, O14, O34, O38)*

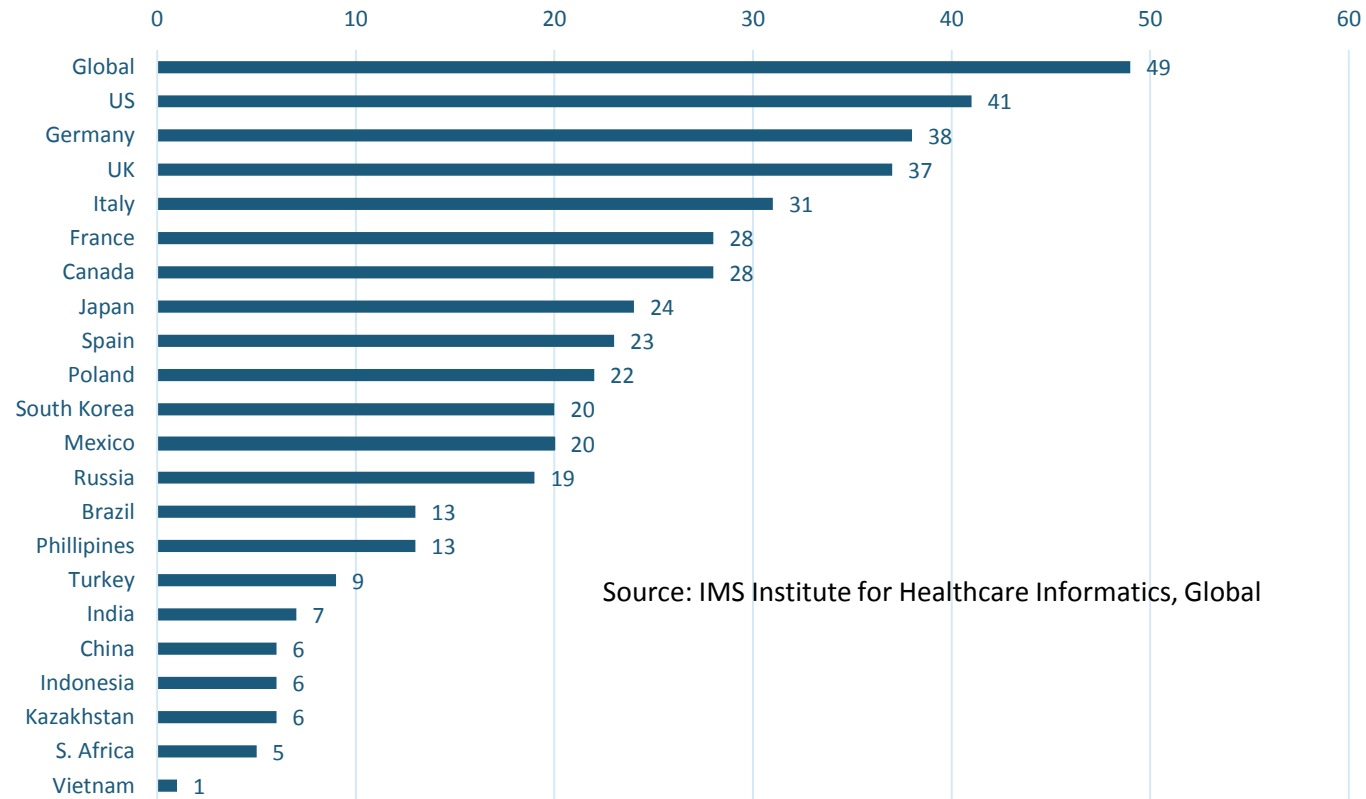
Intellectual property (IP) protection for pharmaceuticals in the developing world is a heavily discussed issue. The debate has only grown more contentious as many formerly poor countries have experienced rapid economic growth and now represent potentially profitable markets for foreign pharmaceutical firms. Partly because of the growing importance of developing countries as consumers for many products, in 1994 all members of the World Trade Organization were required to adopt the Trade Related Intellectual Property Standards (TRIPS). TRIPS was intended to establish uniform IP standards across countries including a product patent system for pharmaceuticals. Many developing countries were given ten years to implement a TRIPS-compliant regime and have only recently created these systems. As a result, little is known about the effects of these policies in developing countries. In this paper, we

<sup>1</sup> Duggan: Department of Economics, Stanford University, 579 Serra Mall, Stanford, CA 94305, and NBER (e-mail: mgduggan@stanford.edu); Garthwaite: Kellogg School of Management, Northwestern University, 2001 Sheridan Road, Evanston, IL 60208, and NBER (e-mail: c-garthwaite@kellogg.northwestern.edu); Goyal: The World Bank, 1818 H Street, NW, Washington, DC 20433 (e-mail: agoyal3@worldbank.org). We are grateful to Preethi Rao for excellent research assistance and to Jen Brown, Meghan Busse, Leemore Dafny, Pascale Dupas, Amy Finkelstein, Margaret Kyle, Grant Miller, Neale Mahoney, Petra Moser, Matt Notowidigdo, Emily Oster, Bhaven Sampat, Heidi Williams, seminar participants at Northwestern University, the Bates White Life Sciences Conference and the 60th Anniversary Congress of the Yrjö Jahnsson Foundation for helpful comments. Duggan thanks the Dean's Research Fund and the Global Initiatives Fund at the Wharton School for support of this research and Goyal thanks the DECRG Research Support Budget grant of the World Bank. We also thank Bhaven Sampat for providing data on patent strength for a sample of products in the Indian market. The views expressed in this paper are solely those of the authors and do not represent the views of any of the institutions mentioned above. The statements, findings, conclusions, views, and opinions contained and expressed in this article are based in part on data obtained under license from IMS Health Incorporated and MIDAS™ (2003–2011). All rights reserved. The statements, findings, conclusions, views, and opinions contained and expressed herein are not necessarily those of IMS Health Incorporated or any of its affiliated or subsidiary entities.  
<sup>2</sup> Go to <http://dx.doi.org/10.1257/aer.20141301> to visit the article page for additional materials and author disclosure statement(s).

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# Regulatory Policy Significantly Affects Drug Launches

Number of 2010-2014 Cancer Medicines That Have Been Launched in Various Regions



Source: IMS Institute for Healthcare Informatics, Global

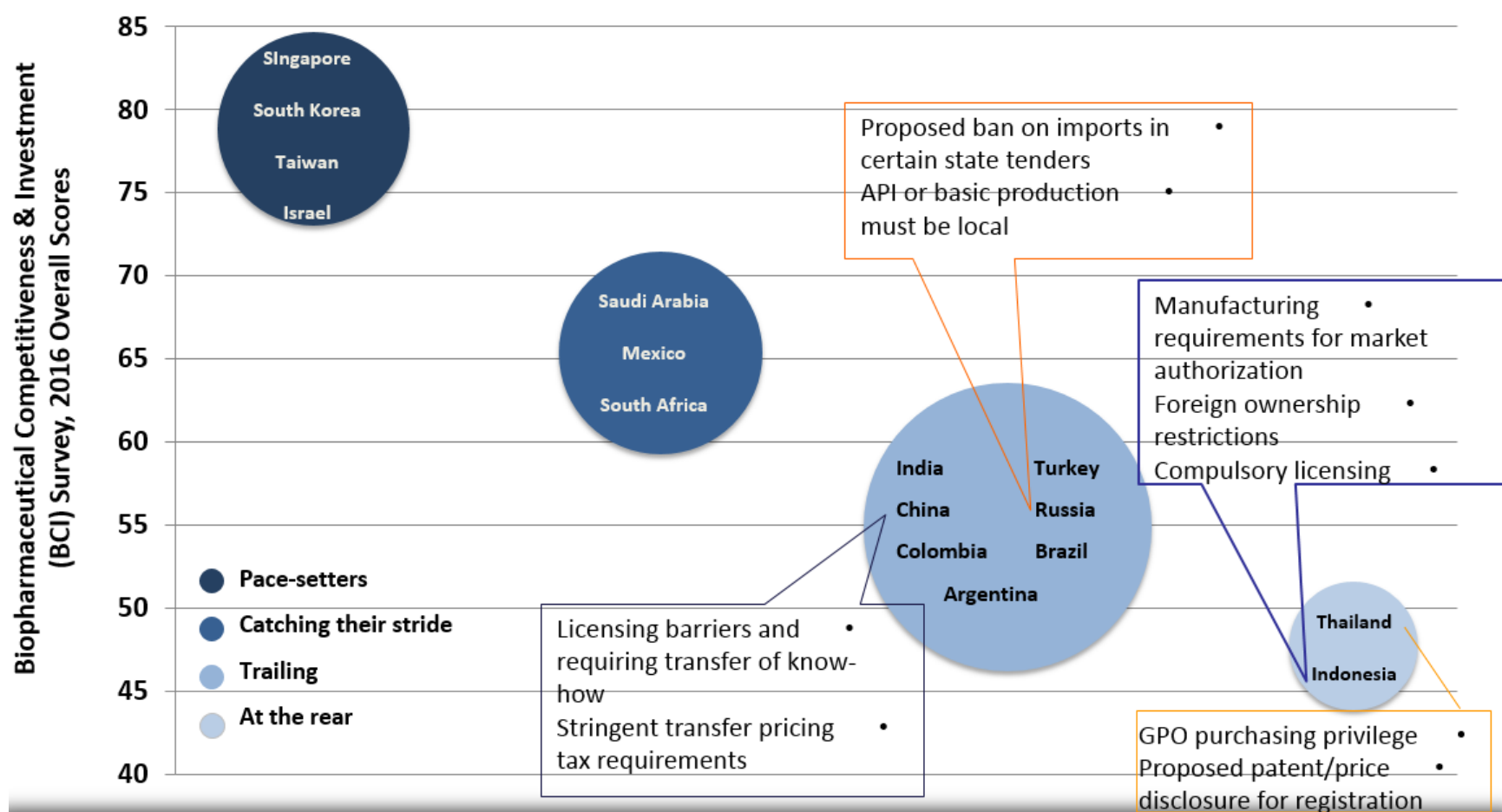
Source: Frank Lichtenberg, "The impact of pharmaceutical innovation on cancer mortality in Mexico, 1998-2014" (Presentation, Mexico City, Mexico, March 30, 2017)

# How Developing Countries Fare in Life-Sciences Innovation



Source: Pugatch Consilium, *The Race for Biopharmaceutical Innovation: BCI Survey 2016*

# Laggards Embrace Compulsion, Not Attraction, Strategies



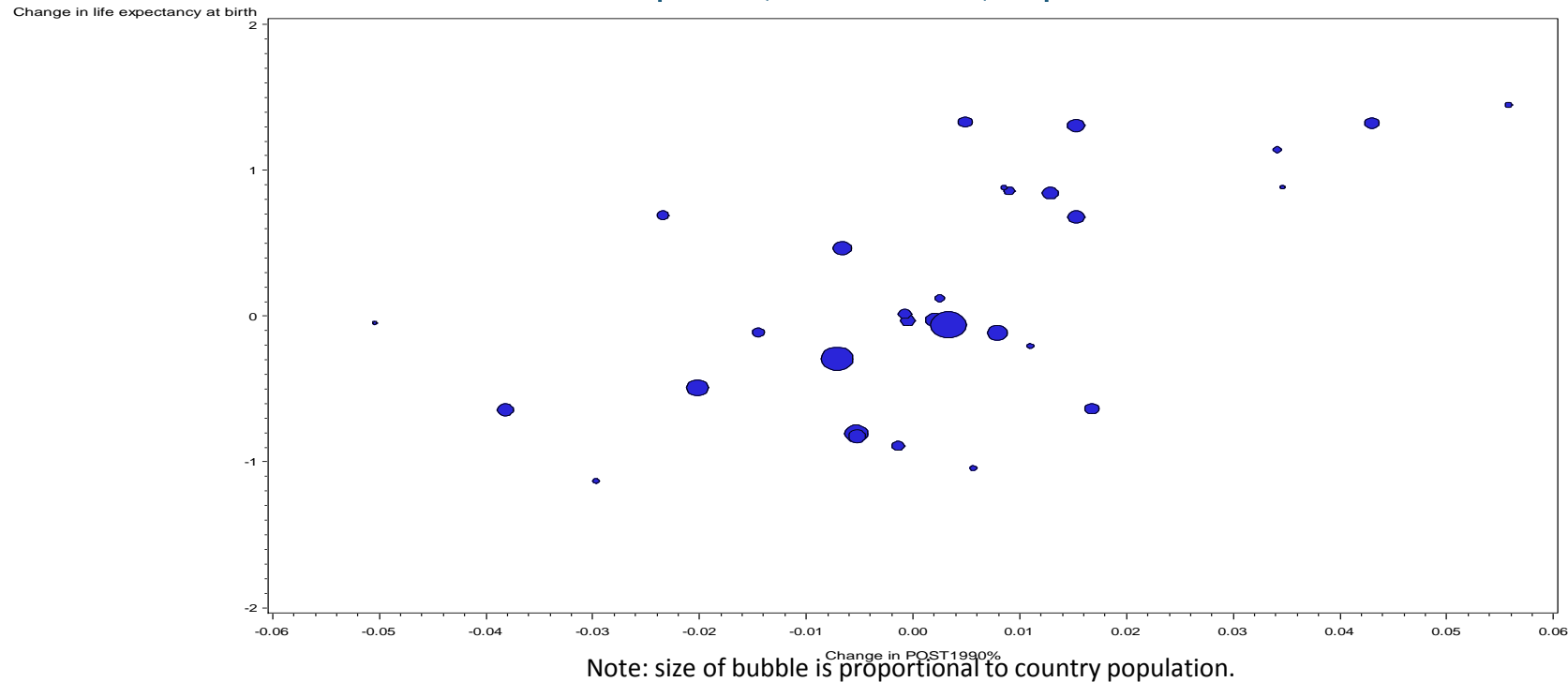
Source: Courtesy Meir Pugatch, The Pugatch Consilium



# Why Life-Sciences Innovation Matters

## Correlation across countries between 2000-2009 change in life expectancy at birth and change in drug vintage

controlling for changes in income, unemployment rate, education, urbanization, health expenditure, immunization rate, HIV prevalence and tuberculosis incidence



**Pharmaceutical innovation accounted for 73% of the 2000-2009 increase in life expectancy at birth in 30 countries (1.27 years of the 1.73 year increase).**

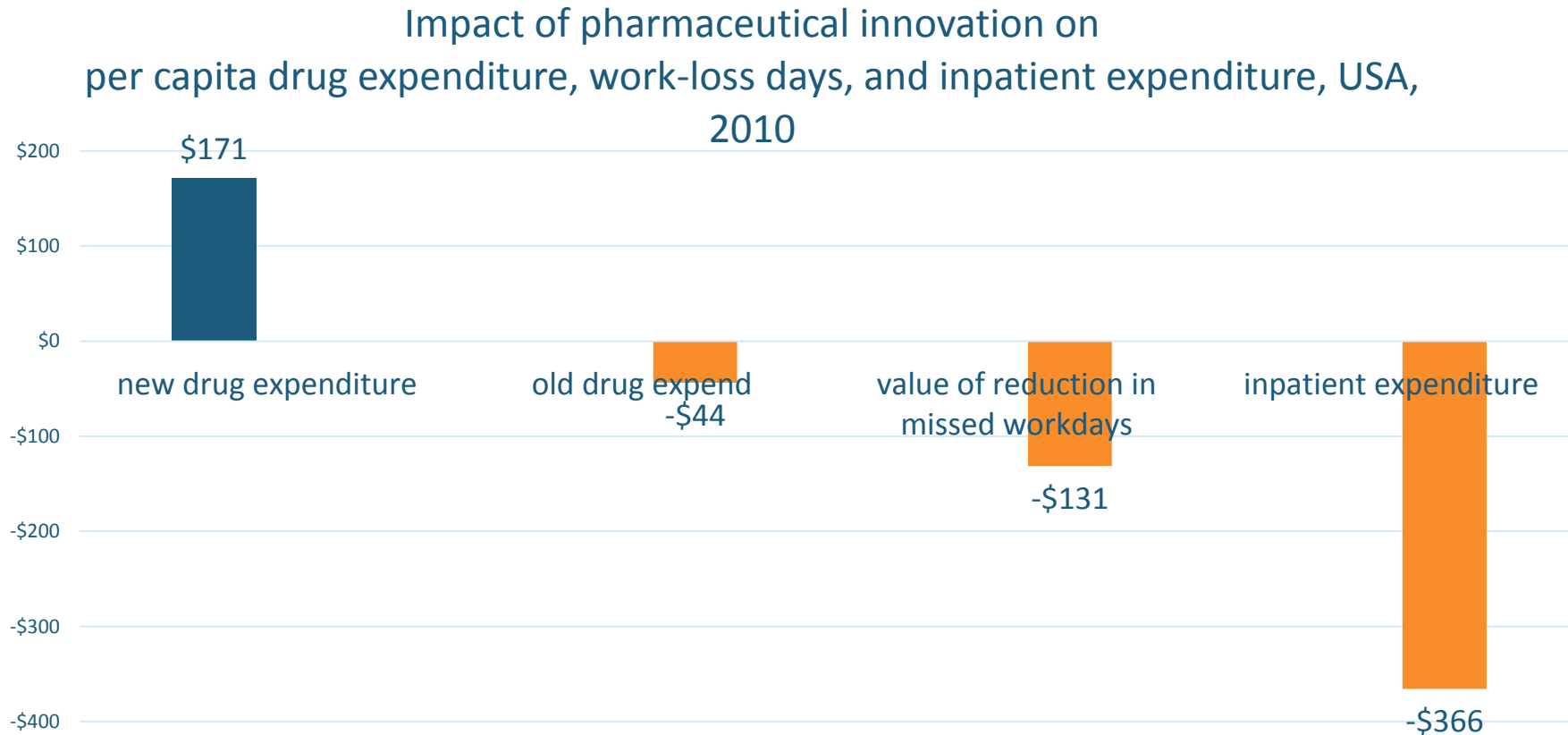
Source: Frank Lichtenberg, *Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009 Health Policy and Technology* 3(1): 36-58, March 2014

# Why Life-Sciences Innovation Matters

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- Helping citizens live longer, healthier lives generates economic benefits.
  - Improvement in U.S. life expectancy from 1970 to 1990 added \$2.8 trillion to U.S. productivity.
  - This equaled \$12,000 per U.S. citizen, per added year of life expectancy.
- Opportunity cost of missing work (especially for chronic diseases)
  - Keeps many out of work, lowers productivity, contributes to absenteeism
- Eliminating heart disease valued at \$48 trillion, curing cancer \$47 trillion; Alzheimer's disease will cost \$1 trillion a year by 2050.

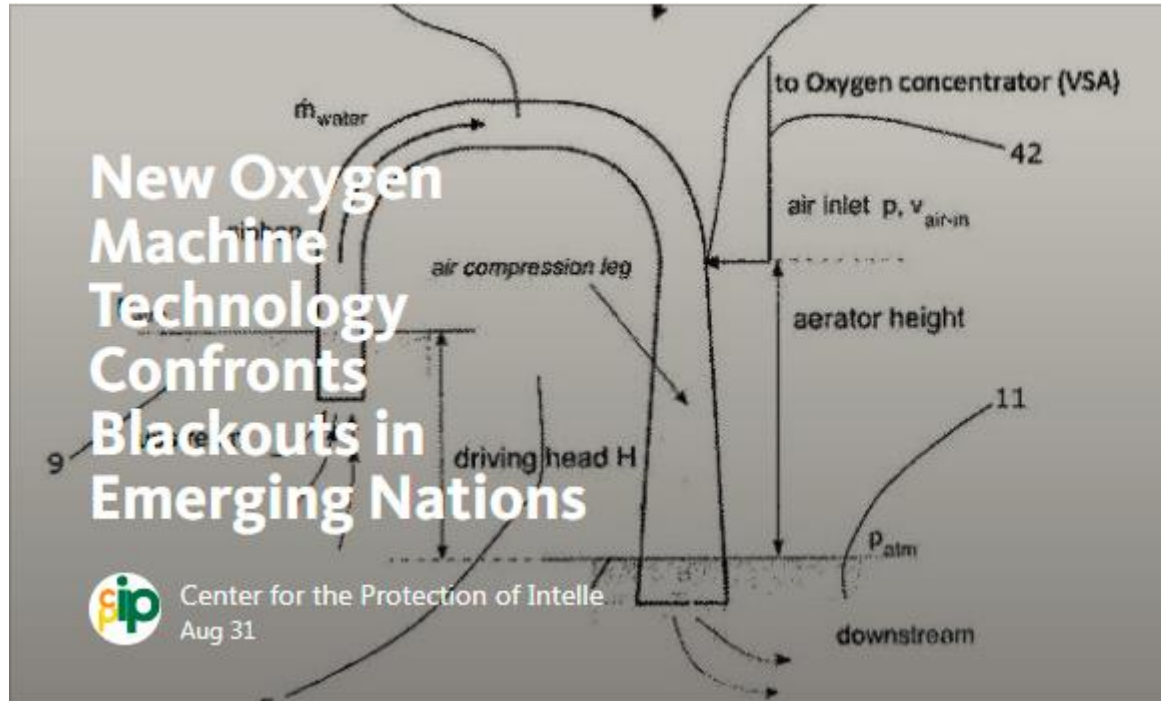
# Investment in Life-Sciences Innovation Pays



“The value of reductions in work loss days and hospital admissions attributable to pharmaceutical innovation was three times larger than the cost of new drugs consumed.”

Source: Frank Lichtenberg, *Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009 Health Policy and Technology* 3(1): 36-58, March 2014

# Innovate4Health Initiative – ITIF and CPIP



<https://medium.com/innovate4health>

# Join the Global Trade and Innovation Policy Alliance

**Global Trade & Innovation Policy Alliance**

ABOUT PRINCIPLES MEMBERS PUBLICATIONS CONTACT

**The Imperative of Protecting Life Sciences Innovation in the TPP**

**The Indian Economy at a Crossroads**

**The False Promise of Data Nationalism**

**Global Innovation Policy Index**

**Digital Trade**  
The False Promise of Data Nationalism  
This report argues that calls to keep data within national borders are misguided and ineffective in making data more secure.

**International Economic Institutions**  
Building the Global Innovation Economy  
This The Futurist article explores reforms that need to be made to global international economic institutions so that they can become greater champions of global innovation.

**Trade and Development**  
A Policymaker's Guide to Spurring ICT Adoption  
ITIF's new guide gives policymakers around the world a policy checklist to spur ICT adoption.

**Trade and Intellectual Property**  
The Imperative of Protecting Life Sciences Innovation in the TPP  
To ensure the Trans-Pacific Partnership (TPP) Agreement creates a framework in which life sciences innovation flourishes throughout the TPP region, it needs to include 12 years of data protection for novel biologic drugs.

**Innovation Mercantilism**  
Green Mercantilism: Threat to the Clean Energy Economy  
Global energy innovation is being undermined by unfair trade practices.

**Trade Agreements**  
The ITA Expansion Deal on the Table Benefits Korea  
Expanding the Information Technology Agreement can bring significant benefits to Korea's economy.

**Trade and Innovation**  
Competitiveness, Innovation and Productivity: Clearing Up The Confusion  
ITIF explains the difference between competitiveness, innovation and productivity in this policy memo.

**Trade and Manufacturing**  
An Alternative to Mercantilism: Manufacturing Extension Services in Latin American and Caribbean Countries  
SME manufacturing extension programs are boosting innovation and growth in Latin American and Caribbean nations.

- Bay Area Council Economic Institute (U.S.)
- C.D. Howe Institute (Canada)
- The Center for Global Enterprise (U.S.)
- Center for Social and Economic Research (Poland)
- Competere (Italy)
- The Free Market Foundation (South Africa)
- Fundación Idea (Mexico)
- Geneva Network (UK)
- ICRIER (India)
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- Swedish Agency for Growth Policy Analysis (Sweden)
- Taiwan Institute for Economic Research
- Taiwan Research Institute
- Tic Tac de la CCIT (Colombia)

# Thank You!

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